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OIPE MAY 2 3 2001 PATENT & TRADEMARK OFFICE

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	TRAUTMAN, et al.	Group Art Unit: 1616
Serial No.:	09/208,813	Examiner: S. Dobson
Filed:	December 9, 1998	**Preliminary Amendment B**
For:	DEVICE FOR ENHANCING TRANSDERMAL AGENT FLUX	
Confirmation No.	8648	

Director of the USPTO
Washington, D.C. 20231

Sir:

In the above-identified application, a Request for Continuing Prosecution application having been filed on March 12, 2001, kindly amend as follows:

05/24/2001 HMOHAMM1 00000116 011173 09208813
01 FC:103 36.00 CH

IN THE CLAIMS

1. (Twice amended). A device for use in introducing or withdrawing an agent through a body surface, comprising:

a thin, flexible sheet-like member having a plurality of microprotrusions extending from a body surface proximal portion of the member; and

a structural support which defines one or more voids for an agent-containing or agent receiving reservoir and which extends substantially across, and makes contact substantially across, a width, length and/or diameter of the member, the support having greater rigidity than the member and wherein the structural support substantially reduces the tendency of the member to deflect upon application of a force to the top of the structural support.

8. (Amended). The device of claim 1, wherein the structural support comprises a plurality of cross-members, the cross-members being spaced no more than about 4 times a distance between adjacent microprotrusions in said microprotrusion member [defines a void for an agent-containing or agent-receiving reservoir].

REMARKS

Applicant's attorney wishes to thank Examiner Shelborne for granting a telephone interview on July 7, 2000. In accordance with the discussion during the interview, Applicant submits this amendment and requests reconsideration of the claim rejections.

The present invention relates to a sheet member (6) having a plurality of tiny microprotrusions (4) which have a size and shape adapted to pierce the outermost stratum corneum layer of the skin. Because of the thin gauge of the sheet member, the sheet member tends to be very flexible. Thus, when a skin piercing force is applied to the skin distal side of the sheet member, the thin sheet member flexes, resulting in uneven penetration by the microprotrusions. The present invention provides a rigid support member which contacts and extends across the length or width of the sheet member. Preferably, the support member extends across the entire area of the sheet member in the region having the microprotrusions. The support member acts to transmit the applied force evenly across the entire length and width of the sheet member so that all of the microprotrusions in the sheet member evenly penetrate the stratum corneum to a consistent depth.

Independent claim 1 has been amended to recite that the support member "defines a void for an agent-containing or agent-receiving reservoir" and "extends across a width or length of the member". Support for these amendments can be found on

CLAIMS:

1. A device for use in introducing or withdrawing an agent through a body surface, comprising:

a member having a plurality of microprotrusions extending from a body surface proximal portion of the member; and

a structural support which contacts and extends across at least a portion of the member, the support having greater rigidity than the member.

2. The device of claim 1, wherein the support has greater rigidity to a force applied perpendicular to the body surface than does the member.

3. The device of claim 1, wherein the support is sufficiently rigid to deflect less than 300 μm under manually applied finger or hand pressing of the device against skin.

4. The device of claim 3, wherein the support deflects less than 50 μm under said pressing.

5. The device of claim 1, wherein the support is sufficiently incompressible to compress less than 250 μm under manually applied finger or hand pressing of the device against skin.

6. The device of claim 5, wherein the support compresses less than 50 μm under said pressing.

7. The device of claim 1, wherein the member comprises a sheet which in use is oriented approximately parallel to the body surface, the sheet having a plurality of openings therein and the plurality of microprotrusions extending from a body proximal surface of the sheet, said microprotrusions being adapted to pierce the body surface.

8. The device of claim 1, wherein the structural support defines a void for an agent-containing or agent-receiving reservoir.

9. The device of claim 7, wherein the reservoir is in agent-transmitting communication with the openings in the sheet.

10. The device of claim 1, wherein the support comprises a peripheral member and a plurality of cross-members.

11. The device of claim 1, wherein the support has a honeycomb structure.

12. The device of claim 1, wherein the support comprises a corrugated sheet.

13. The device of claim 1, wherein the support has a curved surface which contacts the member.

14. The device of claim 13, wherein the curved surface has a shape selected from the group consisting of convex and cylindrical.

15. The device of claim 7, wherein the support comprises a plurality of wavy strips arranged in perpendicular alignment to the sheet.

16. The device of claim 1, wherein the member has a thickness of less than 100 μm.

17. The device of claim 16, wherein the member is comprised of metal.

18. The device of claim 1, wherein the member comprises a sheet having the plurality of microprotrusions extending from a body surface proximal edge of the sheet for piercing the body surface, the sheet when in use being oriented

in an approximately perpendicular relation to the body surface with the body surface proximal edge having the microprotrusions engaging the body surface.

19. The device of claim 18, wherein the sheet has a configuration which defines a void for an agent-containing or agent-receiving reservoir.

20. The device of claim 18, wherein the support contacts a second edge of the sheet, which second edge is opposite to the body surface proximal edge having microprotrusions.

21. A method of maintaining open agent-transmitting pathways through a body surface having the device of claim 1 positioned adjacent thereto, comprising periodically reapplying a body surface directed force to said device.

22. The method of claim 21, wherein said reapplying causes said microprotrusions to repierce the body surface.

23. The method of claim 21, wherein said force is applied manually.

24. The method of claim 21, wherein the structural support comprises an annular member.

25. The method of claim 24, wherein the annular member is a circular, square or rectangular annular member having a diagonal cross-member.

26. The method of claim 21, wherein the structural support has a plurality of cross-members.

27. The method of claim 26, wherein the plurality of cross-members intersect generally in the center of the structural support.

28. The method of claim 21, wherein the structural support comprises:

an outer annular member;

an inner annular member having a diameter less than a diameter of the outer annular member; and

the cross-member joins the inner annular member to the outer annular member.

29. The method of claim 21, wherein the support has greater rigidity to a force applied perpendicular to the body surface than does the member.

30. The method of claim 21, wherein the support is sufficiently rigid to deflect less than 300 μm under manually applied finger or hand pressing of the device against skin.

31. The method of claim 30, wherein the support deflects less than 50 μm under said pressing.

32. The method of claim 21, wherein the support is sufficiently incompressible to compress less than 250 μm under manually applied finger or hand pressing the device against skin.

33. The method of claim 32, wherein the support compresses less than 50 μm under said pressing.

34. The method of claim 21, wherein the member comprises a sheet which in use is oriented approximately parallel to the body surface, the sheet having a plurality of openings therein and the plurality of microprotrusions extending from a body proximal surface of the sheet, said microprotrusions being adapted to pierce the body surface.

35. The method of claim 21, wherein the structural support defines a void for an agent-containing or agent-receiving reservoir.

36 (New). The device of claim 1, wherein the member has one or more peripheral edges and an interior portion surrounded by the one or more peripheral edges, wherein the structural support extends from the one or more peripheral edges and across the interior portion of the member.

37 (New). The device of claim 8, wherein the cross-members define a plurality of voids for an agent-containing or agent-receiving reservoir.

DETAILED ACTION

Claim Rejections - 35 U.S.C. § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.

2. Claims 1-10, 16-26, and 29-35 are rejected under 35 U.S.C. 102(b) as being anticipated by Gerstel et al 3,964,482).

Gerstel et al teach a drug delivery device for percutaneously administering a drug comprising a plurality of projections, and a drug reservoir containing a drug. (Note column 1, lines 6-15). In the drug delivery device, the projections and the reservoir can be constructed as a unit piece or the projections and the reservoir can be fabricated from parts into the drug delivery device. (Note column 3, lines 38-50). In fig. 2, the drug delivery device is formed of two separate parts. One part of this two part drug delivery device is comprised of a plurality of puncturing projections, which are equivalent to applicants' micro protrusions. The other part of the two part drug delivery device is drug reservoir and is positioned and over-layed on base. (Note column 4, lines 22-27, 45-60 and column 5, lines 10-20 and 36-40). An auxiliary purpose of the backing member is to provide support for the device. (Note column 6, lines 49-50). The projections are usually at any angle that corresponds to the angle of the body skin, e.i. 90^0 to the surface. The

projections will be about 5 microns to about 100 microns in length. (Note column 7, lines 36-37 and 64-65). The device can be fabricated with a backing member or backing strip. The backing member can be in a single layer of material, a multi-layer materials.... (Note column 12, lines 53-68). The backing member can be flexible or nonflexible and include coated flexible fibrous backings such as aluminum foil. (Note column 13, lines 7-8 and 14-16). The rigidity of the support layer and the limitations e.i. deflect, incompressible, compresses, pertaining thereto are seen to be inherent without a showing to the contrary.

3. Claims 1-10, 16-26 and 29-35 are rejected under 35 U.S.C. 102(e) as being anticipated by Godshall et al (5,879,326).

Godshall et al teach a drug delivery system that alters the outermost layer of skin to greatly improve the delivery of compounds through the skin. The apparatus includes a cutter having a plurality of micro protrusions and a stop for preventing the apparatus from penetrating the skin beyond a predetermined distance. (Note column 2, lines 50-59; column 3, lines 29-44). The simplest embodiment is a bed of micro cutters attached to a substrate. (Note column 4, lines 1-16). When the device is applied to the patient's skin, it is pressed against the skin and moved laterally in a direction parallel to the surface of the skin. (Note column 4, lines 45-49). It has been found experimentally that a micro cutter having blades with lengths between 50um and 175 um is acceptable. (Note the paragraph bridging columns 4 and 5). The fabrication techniques utilized silicon substrates to form the micro protrusions directly or through molding of plastics/polymers, metals or the like. (Note column 5, line 57-column 6, line 5). The rigidity of the support layer and

the limitations e.i. deflect, incompressible, compresses, pertaining thereto are seen to be inherent without a showing to the contrary.

Claim Rejections - 35 U.S.C. § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 11-15 and 26-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gerstel et al or Godshall et al.

Gerstel et al and Godshall et al are relied upon for the reasons stated above. Gerstel et al and Godshall et al differ from applicants' claimed invention by not specifically teaching the specific shape of the support. However, given the specific teachings of the references, it would have been obvious to one of ordinary skill of the art at the time the invention was made to use the shape of the support without a clear showing of unexpected results. Especially, since Gerstel et al teach at the paragraph bridging columns 12 and 13, that backing member can be a single layer of material, a multi-layer of material, form of precast films, fabrics, other types of laminae bonded together, costed flexible fibrous backings such as nonporous paper, cloth, foil and the like. And Godshall et al teach a substrate of various films, including a wafer.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathryne E. Shelborne whose telephone number is (703) 308-3627. The examiner can normally be reached on Monday-Friday from 7:30 am to 4:00 pm.

DETAILED ACTION

1. Claims 1-35 are pending in this application.

Claim Rejections - 35 U.S.C. § 102

2. Claims 1-10, 16-26 and 29-35 are rejected under 35 U.S.C. 102(b) as being anticipated by Gerstel et al for the reasons stated in the last office action of paper no. 5.

3. Claims 1-10, 16-26 and 29-35 are rejected under 35 U.S.C. 102(e) as being anticipated by Godshall et al for the reasons stated in the last office action of paper no. 5.

Claim Rejections - 35 U.S.C. § 103

4. Claims 11-15 and 26-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gerstel et al in view of Godshall et al for the reasons stated in the last office action of paper no. 5.

Response to Arguments

5. Applicant's arguments filed 7/24/2000 have been fully considered but they are not persuasive.

In response to Applicants' arguments that Godshall contains no disclosure of any structural support member, the microelectronic-like technologies typically first employ the deposition onto a substrate of various films. The substrate is then bulk. This would indicate that some sort of structural support member is being used. (Note column 5, lines 65-6 and column 6, lines 11-14). In response to Applicants' arguments that therefore, Applicants' entire invention and specifically claim 1 which calls for "a structural support which contacts and extends across a width and/or length of the member, the support having greater rigidity than the member" is

nowhere disclosed or suggested in the Godshall patent, the examiner is not convinced that this limitation is not met. Although the limitation is not specifically stated, it appears that it's implied. Otherwise, there would have been no need of the bulk substrate. For this reason, the Godshall reference disclose or at least makes obvious the claimed invention.

In response to Applicants' arguments that the present invention as defined in the now amended claim 1 which recites a structural support which contacts and extends across a width and/or length of the member is neither disclosed in the Gerstel reference, it is noted that Gerstel, at column 4, lines 58-66, teaches that the other part of the two part drug delivery device is drug reservoir positioned and over-layed on base. Again, it appears that the claimed limitation is met. Therefore, this rejection is being maintained and is made final.

Conclusion

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

September 9, 2000

JOHN PAK
PRIMARY EXAMINER
GROUP 1200

Notice of References Cited

Application No.	Applicant(s)		
09/208,813	Trautman et al		
Examiner		Group Art Unit	Page 1 of 1
Kathryne E. Shelborne		1616	

U.S. PATENT DOCUMENTS

	DOCUMENT NO.	DATE	NAME	CLASS	SUBCLASS
A	3,964,482	6/1976	Gerstel et al	128	260
B	5,879,326	3/1999	Godshall et al	604	51
C					
D					
E					
F					
G					
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I					
J					
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FOREIGN PATENT DOCUMENTS

	DOCUMENT NO.	DATE	COUNTRY	NAME	CLASS	SUBCLASS
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NON-PATENT DOCUMENTS

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